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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,806	12/31/2003	Masahito Watanabe	60542(49811)	6518

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EXAMINER

SHIAO, REI TSANG

ART UNIT PAPER NUMBER

1626

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/749,806

Applicant(s)

WATANABE ET AL.

Examiner

Robert Shiao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/09/04, 12/31/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the foreign applications:

JAPAN 2003-9786 with a filing date 01/17/2003; and

JAPAN 2003-71368 with a filing date 03/17/2003.

2. Claims 1-9 are pending in the application.

Information Disclosure Statement

3. Applicant's Information Disclosure Statements, filed on September 09, 2004, and December 31, 2003, have been considered. Please refer to Applicant's copies of the 1449's submitted herein.

Responses to Election/Restriction

4. Applicant's election with traverse of Group I claims 1-9, in part, in the reply filed on October 30, 2006, is acknowledged. Applicants also elect the following species: compound (A) is cyclopentanone; compound (B) is dimethyl malonate; compound (C) is (R)-3-[bis(methoxycarbonyl)methyl]cyclopentanone; and compound (D) is N-methanesulfonyl-1,2-diphenylethylenediamine. The traversal is on the grounds that applicants submit that no unreasonable burden is incurred by search of the claimed subject matter with alternate scope of products than those delineated in Groups I-III. This is found not persuasive, and the reasons are given *infra*.

Claims 1-9 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Claims 1- 9, in part, drawn to processes of making compounds of formula (C), wherein the variables R^1-R^3 independently do not represent a heteromonocyclic or heteropolycyclic group, the variables R^1-R^3 independently are not substituted with a heteromonocyclic or heteropolycyclic group; and wherein the variable R^1-R^{10} of starting material compounds of formula (A), (B), or (D) independently do not represent a heteromonocyclic or heteropolycyclic group, the variables R^1-R^{10} of starting material compounds of formula (A), (B), or (D) independently are not substituted with a heteromonocyclic or heteropolycyclic group thereof.

The withdrawn processes of making comprising compounds of formula (C) contain varying heteromonocyclic or heteropolycyclic group of the variables R^1-R^3 having indolyl, thiazole, azepane, or piperazine moiety, which differ from those of the elected invention having pyridyl moiety, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classifications of these functional groups in the U.S. classification system, i.e., class 548 subclass 469(+) (indolyl), class 548 subclass 146(+) (thiazole), class 544 subclass (336+) (piperazine), class 540 subclass 484(+) (azepane), etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in common structure and have been restricted properly.

The group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct

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inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Claims 1-9, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 1-9, in part, not embraced in above elected subject matter, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for processes making compounds of formula (C) using a ruthenium compound obtained from an optically active nitrogen-containing compound (i.e., formula (D)) and a metal ruthenium, does not reasonably provide enablement for processes making compounds of formula (C) without limitation of an asymmetric metal complex and the metal selected from Group VIII of the periodic table, see claim 1, page 57, lines 15- 17. The specification does not enable any person skilled

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in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Dependent claims 2-9 are also rejected along with claim 1 under 35 U.S.C. 112, first paragraph.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case:

The nature of the invention

The nature of the invention is processes of making compounds of formula (C) using an asymmetric metal complex obtained from an optically active nitrogen-containing compound (i.e., formula (D)) and a metal, wherein the asymmetric metal complex and the metal of Group VIII is not limited.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that a similar metal complex having a nitrogen-containing compound and a metal Fe, see Zhang's US 6,380,392.

The amount of direction or guidance present and the presence or absence of working examples

The only direction or guidance present in the instant specification is the ruthenium compounds on pages 18-42 of the specification. There is no data present in the instant specification for processes of making using an asymmetric metal complex other than ruthenium compounds.

The breadth of the claims

The instant breadth of the rejected claims is broader than the disclosure, specifically, the instant claims include any processes making compounds of formula (C) using an asymmetric metal complex, wherein the asymmetric metal complex and the metal of Group VIII is not limited.

The quantity or experimentation needed and the level of skill in the art

While the level of the skill in the chemical arts is high, it would require undue experimentation of one of ordinary skill in the art to resolve any asymmetric metal complex other than ruthenium compounds. It would also require undue experimentation to obtain any processes, wherein the asymmetric metal complex and the metal is not

limited. The only guidance present in the instant specification is the processes of making compounds of formula (C) using an asymmetric metal complex, wherein the asymmetric metal complex is a ruthenium compound, see pages 18-42 of the specification. There is no guidance or working examples present for constitutional any processes using an asymmetric metal complex other than a ruthenium compound. Therefore, the claims lack enablement for all processes using any asymmetric metal complex other than ruthenium compounds. Replacement of the limitation "an asymmetric metal complex" with the limitation "a ruthenium compound", and replacement of the limitation "a metal of group VIII of the periodic table" with the limitation "a metal of ruthenium" would overcome this rejection.

Claim Objections

6. Claims 1-9 are objected to as containing non-elected subject matter, i.e., heteromonocyclic or heteropolycyclic group, etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the pages 2-3 *supra*.
7. Claims 1, 4-6, and 8-9 are objected to as containing symbols "(" or ")" for the limitation of variables R^1 - R^6 , e.g., see claim 1, line 5. Replacement of the symbol "(" or ")" with a symbol "," would obviate the objection.
8. Claim 9 is objected to as containing a typographic error of the formula (E), see line 6. Replacement of the formula (E) with the formula (F) would obviate the objection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

December 05, 2006